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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,286	06/28/2000	Bruce C. Ross	47-138	4095

23117 7590 08/25/2004
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EXAMINER

BORIN, MICHAEL L

ART UNIT PAPER NUMBER

1631

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

1247-
946

Office Action Summary

Application No.

09/581,286

Applicant(s)

ROSS ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35,36, 38-40,42,43 is/are rejected.
- 7) ☒ Claim(s) 37 and 41 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Status of Claims

1. Amendment filed 03/27/2004 is acknowledged. All original claims, claims 1-34, are canceled. Claims 35-43 are added (claims 1-10, 16-18 are re-written). Claims 35-43 are pending.

2. During telephone conversation with applicant's representative on 08/10/2004, Examiner suggested allowable subject matter directed to polypeptide comprising SEQ ID No. 424 and compositions thereof. As applicant did not provide a response, the following Office action summarizes the outstanding rejections and objections of the pending claims.

Claim Objections

3. Claim 39 is objected as being an essential duplicate of claim 36.

Claim Rejections - 35 USC § 112, first paragraph.

4. Claims 35,36, 38-40,42,43 are rejected under 35 U.S.C. § 112, first paragraph because the specification, while being enabling for polypeptide comprising SEQ ID No. 424 does not reasonably provide enablement for polypeptides comprising amino acid *sequences having* at least 85 or 95% identity to SEQ ID NO:424 or fragments of at least 40 residues of SEQ ID NO:424. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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The specification does not describe common core structure requires for the polypeptides of the claimed genus to exert their common antigenic utility. There does not appear to be sufficient guidance in the specification as filed as to how the skilled artisan would make and use the various polypeptides recited in the instant claims. A person of skill in the art would not know which sequences are essential, which sequences are non-essential, and what particular epitopes identify essential sequences. There is insufficient guidance to direct a person of skill in the art to select particular sequences or sequence lengths as essential for antigenic activity. Without detailed direction as to which peptide sequences are essential to the function of the claimed genus of polypeptides, a person of skill in the art would not be able to determine without undue experimentation which of the plethora of polypeptides encompassed by the instant claims would share the ability to induce specific immune response described for polypeptide SEQ ID No. 424 itself.

Conclusion.

5. No claims are allowed
6. Claims 37,41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr.

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Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

8/20/04

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

